



8-21-08

IFM DAC

**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

**In re Application of:**

Antonino Cattaneo  
Sonia Covaceuszach  
Doriano Lamba

**PCT Application No.:** WO2005/061540

**Presumed U.S. Application No.:** 10/583,618

**For:** METHOD FOR THE  
HUMANIZATION OF ANTIBODIES AND  
HUMANIZED ANTIBODIES THEREBY  
OBTAINED

**Assignee:** Lay Line Genomics

**NOTICE OF EXPRESS MAILING**

Express Mail Mailing Label Number: EV962545427US  
Date of Deposit with USPS: August 19, 2007  
Person making Deposit: Robert J. Gueck

**PETITION TO THE DIRECTOR UNDER 37 C.F.R. 1.181(a)(3)**

Mail Stop Petition  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Sir:

We hereby petition the Office to invoke the supervisory authority of the Director in regard to a previously filed Petition for Access under 37 CFR 1.14(g)(3). Alternatively, if 37 CFR 1.181(a)(3) is not the proper section to bring this petition under, we would like to bring this petition under 37 CFR 1.182 instead.

### **STATEMENT OF FACTS**

On December 14, 2007, we filed a petition for access under 37 C.F.R. 1.14(g)(3) to the file wrapper and contents of the unpublished U.S. patent application accorded application number U.S. 10/583,618. (The petition for access under 37 C.F.R. 1.14(g)(3) is submitted herewith and labeled Exhibit 1). The application is a national phase entry into the U.S. from the published international PCT application WO2005/061540. The international application was published July 7, 2005, and the national stage application was received by the Office over two years ago on June 20, 2006. The application is assigned to Lay Line Genomics and the named inventors in the U.S. are Antonino Cattaneo, Sonia Covaceuszach, and Dorian Lamba. The corresponding international PCT application is entitled "Method for the Humanization of Antibodies and Humanized Antibodies Thereby Obtained."

In response to the petition for access, the Office "elected to provide access to only the electronic copy of the application file" under 37 CFR 1.14(b). (The reply to the petition for access is submitted herewith and labeled Exhibit 2). The Office then states that the electronic copy of the application file is unavailable and will be accessible when the national stage application has published. The Office gives no estimate as to when the publication is expected to occur and dismissed the petition.

On July 16, 2008, we submitted a request for information regarding the status of the U.S. 10/583,618 application. We asked (1) if there was a national entry into the U.S. by the international PCT application WO2005/061540 and (2) what is the current status of the U.S. national entry application or in other words, is the 10/583,618 application still pending in the U.S. The Office responded and stated that there was a national entry on June 20, 2006 and that the application is still pending. (The request for information is submitted herewith and labeled as Exhibit 3, the response to the request is also submitted herewith and is labeled Exhibit 4).

## REMARKS

### Points to be reviewed

Under 37 CFR 1.181(a)(3), we hereby petition to invoke the supervisory authority of the Director to review the decision by the Office to deny us access to the file wrapper and contents of the unpublished U.S. patent application U.S. 10/583,618 as set forth in Exhibit 1 and Exhibit 2. In support of this petition please consider the following remarks.

### The Office has failed to publish U.S. 10/583,618 for over two years

Under 37 CFR 1.14 we have the right to access the file of a national phase entry of a published international application since this file is not held in confidence. We have filed a petition under 37 CFR 1.14 and provided evidence that the international application has been published and designated the U.S. The international filing date of the WO2005/061540 application is December 23, 2004. As indicated in Exhibit 4, the Office received the national entry of the international application on June 20, 2006. Therefore, the Office has had over 2 years to publish the U.S. 10/583,618 application, but has failed to do so and has no estimate as to when the application may be published. We request prompt access to the file wrapper. We believe that more than 2 years is enough time to allow the USPTO to publish U.S. 10/583,618 and ask the Director to facilitate such publication.

### 37 CFR 1.14(b) is not a vehicle to deprive the public of access to a published application

In the response to our petition for access under 1.14, the Office uses 37 CFR 1.41(b) as a reason to deny us access to the U.S. 10/583,618 application. The Office states that it elected to provide access to only the electronic copy of the application file. However, the Office further states that the electronic copy is not available, that it will be available on the Public PAIR system once the application is published, and that there is no estimate as to the possible publication. The Office confuses the discretionary privilege to provide an electronic copy of an application with the right to deny the public access to the application altogether. 37 CFR 1.41(b) does not state that the public's right to access to an application may be denied because the Office elects to provide access to only an electronic copy and that no electronic copy is available. The Office's interpretation of 37 CFR 1.14(b) is especially unreasonable in this case because it was the Office's own two year delay that caused the electronic copy to not be available in the first place. We respectfully submit that the Office may not use 37 CFR 1.14(b) as a vehicle to deprive the public of access to a published application.

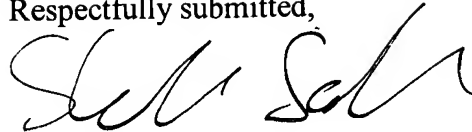
Moreover, 37 CFR 1.14 states that the Office may provide access “to only an electronic copy of the specification, drawings, and file contents of the application.” However, the regulation does not state that the Office has further discretion to pick only one particular method of providing the electronic copy of the file contents, such as the Public PAIR system. In its response to our petition to access the U.S. 10/583,618 application, the Office states that the electronic copy will be available on the Public PAIR system once the U.S. 10/583,618 application publishes. However, we respectfully assert that if the Office has any electronic copy of the file contents of the U.S. 10/583,618 application then this copy must be provided under 37 CFR 1.14 and 1.14(b). 37 CFR 1.14(b) refers to “an electronic copy” and does not refer to “an electronic copy accessible on the Public PAIR system.” Therefore, 37 CFR 1.14(b) does not give the Office the additional discretionary privilege to choose one specific electronic copy and only make it available via one specific method. If the Office has any electronic copy of the U.S. 10/583,618 application file contents then such electronic needs to be provided to us under 37 CFR 1.14(b). Furthermore, if the Office has no electronic copy of the U.S. 10/583,618 application file, then a paper copy should be provided. The Office may not use their own delay in publishing the U.S. 10/583,618 application as a reason for not having an electronic copy of the U.S. 10/583,618 application after the Office elects to only provide an electronic copy.

Action requested

We hereby request (1) access to the file wrapper and contents of the unpublished U.S. patent application U.S. 10/583,618 and/or (2) prompt publication of the U.S. 10/583,618 application.

Should a fee for this request be necessary, the Commissioner is authorized to charge the fee to deposit account 20-1469 and to refund money onto the account shall it be necessary to do so. If it is possible to receive the status information via electronic submission, please send the electronic submission to [ssoller@traskbritt.com](mailto:ssoller@traskbritt.com).

Respectfully submitted,



Steffen Soller

Registration No. 62,497

Attorney

TRASKBRITT, P.C.

P.O. Box 2550

Salt Lake City, Utah 84110-2550

Telephone: 801-532-1922

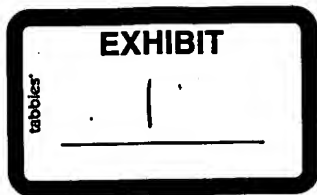
Date: August 19, 2008

Enclosure: Exhibit 1 - petition for access under 37 C.F.R. 1.14(g)(3)

Exhibit 2 – reply to the petition for access under 37 C.F.R. 1.14(g)(3)

Exhibit 3 – request for information

Exhibit 4 – reply to the request of information



**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

**In re Application of:**

Antonino Cattaneo  
Sonia Covaceuszach  
Doriano Lamba

**PCT Application No.:** WO2005/061540

**Presumed U.S. Application No.:** 10/583,618

**For:** METHOD FOR THE  
HUMANIZATION OF ANTIBODIES AND  
HUMANIZED ANTIBODIES THEREBY  
OBTAINED

**Assignee:** Lay Line Genomics

**NOTICE OF EXPRESS MAILING**

Express Mail Mailing Label Number: \_\_\_\_\_

Date of Deposit with USPS: \_\_\_\_\_

Person making Deposit: \_\_\_\_\_

**PETITION FOR ACCESS UNDER 37 C.F.R. 1.14(g)(3)**

Office of PCT Legal Administration  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Sir:

I request access under 37 C.F.R. 1.14(g)(3) to the file wrapper and contents of the unpublished U.S. patent application believed to be filed under application number U.S. 10/583,618. The application is a national phase entry into the U.S. from the published international PCT application WO2005/061540. The application is assigned to Lay Line Genomics and the named inventors in the U.S. are Antonino Cattaneo, Sonia Covaceuszach, and Doriano Lamba. The corresponding international PCT application is entitled "Method for the Humanization of Antibodies and Humanized Antibodies Thereby Obtained."

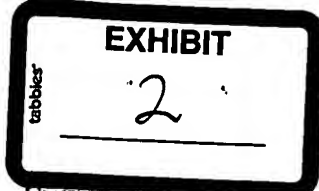
A request under 37 C.F.R. 1.14(g)(3) "must be in the form of a written request including

a showing that the publication of the application has occurred and that the U.S. was designated.” MPEP 110, page 100-21. Such a showing should preferably be in the form of the submission of a copy of the front page of the published international application. *Id* at page 100-22. Additionally, requests for copies of international application files must also be accompanied by the appropriate fee under 37 CFR 1.19(b). *Id*. As such, a copy of the front page of the international published application WO2005/061540 is hereby included as Exhibit 1 showing that the international application was published July 07, 2005. The U.S. designation is marked on Exhibit 1. This request is for an electronic submission of the file wrapper and contents with respect to the search copy. The appropriate fee under 37 CFR 1.19(b)(1)(iii)(B) of \$55 is hereby included. Should this amount be insufficient for any reason, the Commissioner is authorized to charge the fee to deposit account 20-1469. Please send the electronic submission to ACTurner@traskbritt.com.

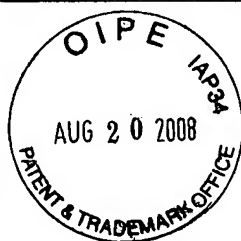
Respectfully submitted.  
ORIGINAL SIGNED BY  
ALLEN C. TURNER

Allen C. Turner  
Registration No. 33,041  
Attorney  
TRASKBRITT, P.C.  
P.O. Box 2550  
Salt Lake City, Utah 84110-2550  
Telephone: 801-532-1922

Date: December 14, 2007



UNITED STATES PATENT AND TRADEMARK OFFICE



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TRASKBRITT, P.C.

COMMISSIONER FOR PATENTS  
UNITED STATES PATENT AND TRADEMARK OFFICE  
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ALEXANDRIA, VA 22313-1450  
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TRASKBRITT, P.C.  
P.O. BOX 2550  
SALT LAKE CITY, UT 84110-2550

In re Application of CATTANEO et al :  
U.S. Application No.: 10/583,618 :  
PCT Application No.: PCT/IT2004/000722 :  
Int. Filing Date: 23 December 2004 :  
Priority Date Claimed: 24 December 2003 :  
For: METHOD FOR THE HUMANIZATION OF :  
ANTIBODIES AND HUMANIZED :  
ANTIBODIES THEREBY OBTAINED :

DECISION

This is in response to applicant's "Petition for Access Under 37 C.F.R. 1.14(g)(3).

Pursuant to 37 CFR 1.14(b), the Office has elected to provide access to only the electronic copy of the application file. At present, the electronic copy of the application file is unavailable. The electronic copy of the present application file will be accessible on the Office's Public Pair system (<http://portal.uspto.gov/external/portal/pair>) when the national stage application has published. There is no estimate as to when publication of the present application is expected to occur.

For the reasons above, the petition under 37 CFR 1.14 is DISMISSED without prejudice.

If reconsideration on the merits of the petition is desired, a proper response must be filed within TWO (2) MONTHS from the mail date of this decision.

Please direct further correspondence with respect to this matter to Mail Stop PCT, Commissioner for Patents, Office of PCT Legal Administration, P.O. Box 1450, Alexandria, Virginia 22313-1450, with the contents of the letter marked to the attention of the Office of PCT Legal Administration.

*Bryan Lin*  
Bryan Lin  
PCT Legal Examiner  
PCT Legal Office

Telephone: 571-272-3303  
Facsimile: 571-273-0459





**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

**In re Application of:**

Antonino Cattaneo  
Sonia Covaceuszach  
Doriano Lamba

**PCT Application No.:** WO2005/061540

**U.S. Application No.:** 10/583,618

**For:** METHOD FOR THE  
HUMANIZATION OF ANTIBODIES AND  
HUMANIZED ANTIBODIES THEREBY  
OBTAINED

**Assignee:** Lay Line Genomics

SUBMITTED BY FAX

**REQUEST FOR INFORMATION ON STATUS OF AN APPLICATION**

Office of PCT Legal Administration  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Sir:

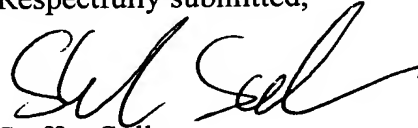
I would like to request information regarding an unpublished U.S. patent application filed under application number 10/583,618. The application is a national phase entry into the U.S. from the published international PCT application WO2005/061540. The application is assigned to Lay Line Genomics and the named inventors in the U.S. are Antonino Cattaneo, Sonia Covaceuszach, and Doriano Lamba. The corresponding international PCT application is entitled "Method for the Humanization of Antibodies and Humanized Antibodies thereby obtained."

The information requested is: (1) was there a national entry into the U.S. by the international PCT application WO2005/061540 and (2) what is the current status of the U.S.

national entry application or in other words, is the (10/583,618) application still pending in the U.S.?

In support of the request for information a copy of the front page of the international published application WO2005/061540 is hereby included showing that the international application was published July 07, 2005. Should a fee for this request be necessary, the Commissioner is authorized to charge the fee to deposit account 20-1469 and to refund money onto the account shall it be necessary to do so. If it is possible to receive the status information via electronic submission, please send the electronic submission to [ssoller@traskbritt.com](mailto:ssoller@traskbritt.com).

Respectfully submitted,



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Attorney

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Fax: 801-531-9168

Date: July 16, 2008

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property  
Organization  
International Bureau



(43) International Publication Date  
7 July 2005 (07.07.2005)

PCT

(10) International Publication Number  
**WO 2005/061540 A3**

(51) International Patent Classification<sup>7</sup>: **C07K 16/00**,  
16/46, 16/28, 16/22, G06F 19/00

(21) International Application Number:  
PCT/IT2004/000722

(22) International Filing Date:  
23 December 2004 (23.12.2004)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:  
RM2003000601 24 December 2003 (24.12.2003) IT

(71) Applicants (for all designated States except US): **LAY LINE GENOMICS S.P.A.** [IT/IT]; Via di Castel Romano, 100, I-00128 Roma (IT). **SCUOLA INTERNAZIONALE SUPERIORE DI STUDI AVANZATI-SISSA** [IT/IT]; Via Beirut, 2/4, I-34014 Trieste (IT).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **CATTANEO**, Antonio [IT/IT]; c/o Lay Line Genomics S.p.A., Via di Castel Romano, 100, I-00128 Roma (IT). **COVACEUSZACH**, Sonia [IT/IT]; c/o Lay Line Genomics S.p.A., Via di Castel Romano, 100, I-00128 Roma (IT). **LAMBA**, Dorian [IT/IT]; c/o Lay Line Genomics S.p.A., Via di Castel Romano, 100, I-00128 Roma (IT).

(74) Agents: **CAPASSO**, Olga et al.; De Simone & Partners S.P.A., Via Vincenzo Bellini 20, I-00198 Roma (IT).

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD).

**Published:**

- with international search report
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

(88) Date of publication of the international search report:  
22 September 2005

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: **METHOD FOR THE HUMANIZATION OF ANTIBODIES AND HUMANIZED ANTIBODIES THEREBY OBTAINED**

(57) Abstract: Method for the humanization of the VH and VL variable regions of an animal antibody of known sequence, humanized animal antibody obtainable according to the method, in particular anti-NGF and anti-TrkA humanized animal antibodies.

WO 2005/061540 A3



UNITED STATES PATENT AND TRADEMARK OFFICE

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Commissioner for Patents  
United States Patent and Trademark Office  
P.O. Box 1450  
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JUL 21 2008

TRASKBRITT, P.C.



Steffen Soller  
TRASKBRITT, PC  
P.O. Box 2550  
Salt Lake City, UT 84110-2550

Dear Mr. Soller:

This letter is in response to your communication filed 16 July 2008, requesting the status of whether any U.S. applications claim priority to WO 2005/061540 (PCT/IT04/00722). The U.S. Patent and Trademark Office records appear to show a U.S. national stage application was accorded U.S. application No. 10/583,618 received 20 June 2006, and the application is **pending** as to the United States. There appear to be no other U.S. applications claiming priority to PCT/IT04/00722, or U.S. application No. 10/583,618.

Wanda Banks  
Paralegal Specialist  
Office of PCT Legal Administration  
Tel: (571) 272-3277

WGB/wgb